



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5436]

Electronic Study Data Submission; Data Standards; Support for Version Update of World Health Organization Drug Global

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing support for the most current B3-format annual version of the World Health Organization (WHO) Drug Global (WHODG) (formerly named WHO Drug Dictionary) (available at <https://www.who-umc.org>), end of support for earlier versions of WHODG, and an update to the FDA Data Standards Catalog (Catalog) for study data provided in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and certain investigational new drug applications (INDs) to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER).

ADDRESSES: You may submit either electronic or written comments at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third

party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-5436 for "Electronic Study Data Submission; Data Standards; Support for Version Update of World Health Organization Drug Global." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1115, Silver Spring, MD 20993-0002, 301-796-5333, email: cderndatastandards@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

On December 17, 2014, FDA published a final guidance for industry entitled “Providing Regulatory Submissions in Electronic Format--Standardized Study Data” (eStudy Data Guidance), posted on FDA’s Study Data Standards Resources webpage at <https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>. The eStudy Data Guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act for study data contained in NDAs, ANDAs, BLAs, and certain INDs to CBER or CDER by specifying the format for electronic submissions. The initial timetable for the implementation of electronic submission requirements for study data was December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a *Federal Register* notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

FDA currently supports the use of WHODG for the coding of concomitant medications in studies submitted to CBER or CDER in NDAs, ANDAs, BLAs, and certain INDs in the electronic common technical document format. Generally, the studies included in a submission

are conducted over many years and may have used different WHODG versions to code concomitant medications. The expectation is that sponsors and applicants will use the most current B3-format annual version of WHODG at the time of study start. However, there is no requirement to recode earlier studies. The transition date for support of the most current B3-format annual version of WHODG is March 15, 2018. Although the use of the current B3-format annual version of WHODG is supported as of this *Federal Register* notice and sponsors or applicants are encouraged to begin using it, the use of the most current B3-format annual version will only be required in submissions for studies that start after March 15, 2019. The Catalog will list March 15, 2019, as the “date requirement begins.” The Study Data Technical Conformance Guide provides additional information and recommendations on the coding of concomitant medications

(<https://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm384744.pdf>).

FDA support for earlier versions of WHODG will end for studies that start after March 15, 2019. The Catalog will be updated to list March 15, 2019, as the “date support ends.” Studies that start after March 15, 2019, will be required to use the most current B3-format annual version of WHODG.

Dated: October 18, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-23029 Filed: 10/23/2017 8:45 am; Publication Date: 10/24/2017]